

7. TAP waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Settlement Agreement bars a remedy sought in such criminal prosecution or administrative action. Provided, however, that nothing in this paragraph is intended to, or will operate to, limit the scope of paragraph 5, in which the state of New York agrees not to prosecute or investigate TAP for certain conduct.

8. The Settlement Amount that TAP must pay pursuant to Paragraph 1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the state of New York's Medicaid program where such denial resulted from the Covered Conduct. If applicable, TAP agrees not to resubmit to the program any previously denied claims where such denial resulted from the Covered Conduct and agrees not to appeal any such denials of claims.

9. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity, including but not limited to any individual or entity that purchased Lupron from TAP.

10. Nothing in any provision of this Agreement constitutes an agreement by the state of New York concerning the characterization of the Settlement Amount for purposes of the state internal revenue laws.

11. In addition to all other payment and responsibilities under this Agreement, TAP agrees to pay all reasonable travel costs and expenses of the state negotiating team. TAP will

pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units after all Participating States execute this Agreement.

12. TAP covenants to cooperate fully and truthfully with the state of New York in any ongoing investigation or investigation commenced within five years of the execution of this Agreement of individuals and entities not specifically released by this Agreement (including any parties with whom TAP has or has had a business or professional relationship, including but not limited to vendors, contractors, partners, joint venturers, physicians, and referral sources) relating to the Covered Conduct. More specifically, upon reasonable request from the state of New York:

(a) TAP will make reasonable efforts to facilitate access to, and encourage the cooperation of, its current and former directors, officers, and employees for interviews and testimony relating to the Covered Conduct, consistent with the rights and privileges of such individuals. To encourage the cooperation of such individuals, TAP agrees to advise such individuals in writing that the state of New York wishes to interview them or seek their testimony, and that the individuals' cooperation is in the best interest of TAP. Cooperation provided pursuant to this subparagraph will include identification of witnesses who, to TAP's knowledge, may have material information related to the state of New York's inquiry. The testimony referred to in this paragraph includes, but is not limited to, testimony deemed necessary by the state of New York or a court to identify or establish the source, original location, authenticity, or other evidentiary foundation for any documents and to authenticate such documents in any criminal, civil and administrative investigations and proceedings in which the state of New York is involved.

(b) TAP will provide copies of non-privileged documents and records in its possession, custody or control relating to the Covered Conduct and relating to the subject of the state of New York's inquiry. In connection with this, TAP shall provide such technical assistance as is necessary and reasonable to facilitate the state of New York's access to any computerized information covered by this Paragraph.

Nothing in this agreement shall be construed as a waiver by TAP of its attorney-client privilege or work product privilege. Notwithstanding that fact, the existence of any such privilege does not affect TAP's obligation to comply with this Agreement.

13. Notwithstanding any provision of this Agreement, TAP is not required to (1) request of its present or former officers, directors, employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) take any action against its directors, employees or agents for following their attorney's advice or for failing to submit to an interview or otherwise cooperate with the state of New York; or (3) waive any privilege or claim of work product. The failure of any individual to submit to an interview or otherwise to refuse to cooperate with the state of New York shall not constitute a breach of this agreement by TAP.

14. The state of New York acknowledges TAP's cooperation in the state of New York's investigation of drug pricing practices and agrees to communicate the nature and extent of this cooperation to other parties upon the request of TAP. The making of this Agreement, and TAP's provision of information pursuant to it, shall not be construed by the state of New York as a basis for the exclusion of any of TAP's products from the state of New York's formulary.

15. TAP represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

16. TAP has entered into a Corporate Integrity Agreement ("CIA") with HHS-OIG. TAP acknowledges that the state of New York may gain access to and use the pricing information provided by TAP under the CIA, provided that the state of New York meets its obligations relating to the use and confidentiality of that information as set forth in this Agreement. TAP acknowledges that the CIA does not preclude the state from taking any appropriate action against TAP for future conduct under the state of New York's laws. The state of New York hereby agrees to abide by all confidentiality provisions and restrictions contained in the CIA and to afford all such information the maximum degree of confidentiality permitted by law.

17. TAP shall report directly to the Medicaid Program for the state of New York the average sale price, as defined below, for pharmaceutical and other products for which the Medicaid Program for the state of New York provides reimbursement (hereafter "Government Reimbursed Products").

(a) AVERAGE SALE PRICE DEFINITION: For purposes of this Agreement, "average sale price" means, with respect to each dosage form, strength and volume of the Government Reimbursed Product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package) the average of all final sales prices charged by TAP for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding direct sales to hospitals. (Those purchasers for which the sales are included in the calculation of average sale price are hereafter referred to as the "Relevant Purchasers".) The prices identified in the calculation of the average sale price should be net of

all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates¹; and all other price concessions provided by TAP to any Relevant Purchaser that result in a reduction of the ultimate cost to the purchaser.

Notwithstanding the foregoing, the average sale price shall not include the value of bona fide charity care or grants.

TAP shall report the average sale price by National Drug Code ("NDC") for each Government Reimbursed Product identified by TAP's NDC. The average sale price reported shall be properly weighted to reflect the volume of sales at each sale price, *i.e.*, for each NDC, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by TAP to a Relevant Purchaser, net of all price reductions identified above, for a Government Reimbursed Product in a quarter by the total number of units of that product sold in that quarter.

(b) TIME FRAME: Except as otherwise noted below, thirty (30) days after the last day of each calendar quarter, TAP shall report, in accordance with section 17.a. above, the average sale prices of each of its Government Reimbursed Products identified by TAP's NDC to: (1) the Medicaid programs of those States who have executed a state settlement agreement with TAP; and (2) First DataBank Inc.² solely for the purpose of reporting pricing information

¹ The term "rebate" as used in this paragraph does not include any payments made by TAP to the States pursuant to the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8)

² If appropriate to reflect changes in the sources from which the Medicaid programs for the Participating States receive pricing information, TAP agrees that, upon the receipt of a written request by any of the Participating States, TAP will report the required information to a drug pricing reporting source other than, and in addition to, First DataBank, provided that the price reporting source agrees to protect the confidentiality of TAP's pricing information in a written agreement containing reasonable provisions equivalent to the confidentiality provisions governing the submission of pricing information to First Data Bank.

based on those average sale prices to the Medicaid Programs of those States that have executed a state settlement agreement. The first such report of average sale prices shall be made no later than 30 days after the end of the first full calendar quarter following the Effective Date of the CIA.

(c) CERTIFICATION: With each report of price information TAP sends to the Medicaid Program for the state of New York, an appropriate employee or agent of TAP will certify that the price information reported has been reported to First DataBank, or any successor or alternative reporting agency, and that the price information has been calculated in accordance with the methodology described in this Agreement. Said certification shall be in the form annexed to this Agreement as Exhibit "A". TAP agrees that this certification by an appropriate employee or agent of TAP constitutes a certification by TAP.

(d) DOCUMENT RETENTION: TAP shall retain all supporting work papers and documentation relating to the average sale price of its Government Reimbursed Products for eight years after the effective date of the CIA, and, to the extent not protected by appropriately asserted privileges, shall make such documentation available for inspection by the MFCU for the state of New York, or a duly authorized representative of the MFCU, pursuant to the confidentiality provisions set forth in paragraph 18 below.

(e) TIME PERIOD. TAP agrees to submit average sale price in accordance with this Agreement for a period of seven years from the effective date of the CIA.

18. (a) TAP and the state of New York acknowledge that the pricing information provided by TAP is considered to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of TAP. It is

further understood that all information provided by TAP shall be made available to the state of New York's MFCU upon request. The state of New York hereby agrees to afford to the pricing information disclosed by TAP the maximum degree of confidentiality permitted by law.

(b) The Medicaid Program of the state of New York has been advised by the MFCU of the purpose and use of this information. The parties acknowledge that this information may be relied upon by the state of New York in establishing reimbursement rates for TAP products, provided however the state of New York will not change reimbursement rates for any TAP product based on this information without conducting meaningful review for all government-reimbursed therapeutically similar products.

19. Unless otherwise stated in writing subsequent to the execution of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

STATE PHARMACY MANAGER
[For the submission of Average Sale Price Data]:

Office of Medicaid Management, D.O.H.
40 Marlboro Rd.
Delmar, NY 12054

STATE MEDICAID FRAUD CONTROL UNIT
[For legal notices and other purposes]:

MFCU of New York
Office of the Attorney General
120 Broadway, 13th Fl.
New York, NY 10271

TAP

Legal Department
TAP Pharmaceutical Products Inc.
675 N. Field Drive
Lake Forest, IL 60045

20. The undersigned TAP signatory represents and warrants authorization by the Board of Directors to execute this Agreement. The undersigned state of New York signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the state of New York through their respective agencies and departments.

21. This Agreement is governed by the laws of the state of New York.

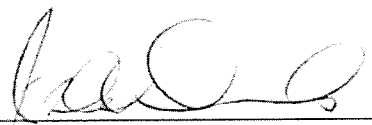
22. This Agreement is effective on the date of signature of the last signatory to the Agreement.

23. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties; provided, however, this Agreement shall not apply to the products of an acquiring company or a company merging with TAP except to the extent such company, as a result of the acquisition of or merger with TAP, becomes involved in the sales, marketing or pricing of, or Medicaid Drug Rebate program obligations associated with, Government Reimbursed Products (as defined in this Agreement) originally manufactured by TAP prior to the merger or acquisition, in which case the obligations of this agreement shall apply only to those products which had been Government Reimbursed Products when they were manufactured by TAP.

24. This Agreement constitutes the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of the Parties. As to Paragraph 1 only, TAP and the NAMFCU TAP Negotiating Team may agree in writing to amend this Agreement by (1) extending beyond 200 days the time in which all Participating States must execute settlement agreements and/or (2) reducing the number and identity of Participating States that must return executed state settlement agreements before funds are disbursed from escrow.

25. Each party agrees to perform any further acts and to execute and deliver any further documents reasonably necessary to carry out this Agreement. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.


For the State of New York:

By: 

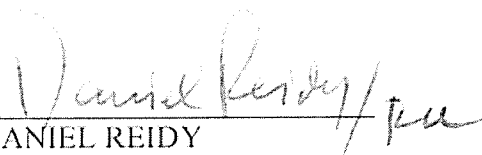
Dated: 12/25/01

Title: _____
JOSÉ MALDONADO
Deputy Attorney General


TAP PHARMACEUTICAL PRODUCTS INC.

By: 
H. THOMAS WATKINS
President
TAP Pharmaceutical Products Inc.

Dated: 12/3/01

By: /pu
DANIEL REIDY
Jones, Day, Reavis & Pogue
77 West Wacker
Chicago, Illinois 60601
Counsel to TAP Pharmaceutical Products Inc.

Dated: 12/4/01

By: /pu
JOSEPH SAVAGE
Testa, Hurwitz & Thibault, LLP
125 High Street
Boston, MA 02110
Counsel to TAP Pharmaceutical Products Inc.

Dated: 12/4/01

EXHIBIT 'A' CERTIFICATION FORM

CERTIFICATION

The undersigned, an agent of TAP Pharmaceutical Products Inc., hereby certifies that the attached average sale price information has been communicated to First Databank or any successor or alternative reporting agency, and that it has been calculated in accordance with the methodology described in the State Settlement Agreement and as further described in TAP's Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services.

Signed _____

Title _____

Date _____